IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC and JANSSEN BIOTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-192 (CFC)
	)	CONSOLIDATED
FRESENIUS KABI USA, LLC, et al.,	)	
Defendants.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT AGAINST SHILPA AND SUN

Plaintiffs Pharmacyclics LLC ("Pharmacyclics") and Janssen Biotech, Inc. ("Janssen"), (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Shilpa Medicare Limited ("Shilpa"); and Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. (collectively, "Sun"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Shilpa's and Sun's recent submissions to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Applications ("ANDAs") seeking approval to market generic versions of Plaintiffs' highly successful pharmaceutical product IMBRUVICA®, prior to the expiration of patents listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for IMBRUVICA®. Shilpa has submitted ANDA No. 211261 ("Shilpa's ANDA") which seeks approval to market a generic version of IMBRUVICA®, prior to the expiration of the U.S. Patent Nos. 9,296,753 ("the '753 Patent") 9,725,455 ("the '455

Patent"); 10,125,140 ("the '140 Patent"); and 10,106,548 ("the '548 Patent"). Sun has submitted ANDA No. 211319 ("Sun's ANDA") which seeks approval to market a generic version of IMBRUVICA®, prior to the expiration of the '753, '455, '140, and '548 Patents, and U.S. Patent Nos. 8,999,999 ("the '999 Patent"); 9,801,881 ("the '881 Patent"); 9,801,883 ("the '883 Patent").

IMBRUVICA®

2. IMBRUVICA® (ibrutinib) is a ground-breaking drug which covalently binds to a protein called Bruton's tyrosine kinase ("BTK"), thereby irreversibly inhibiting BTK's activity.

3. BTK is a key signaling molecule in the pathway that leads to B-cell growth and maturation following activation of the B-cell receptor. Abnormalities in the B-cell receptor signaling pathway can lead to uncontrolled cell growth and cause cancers of the blood and bone marrow. IMBRUVICA® is the first FDA-approved BTK inhibitor.

4. Pharmacyclics invested hundreds of millions of dollars in the development of IMBRUVICA®. Pharmacyclics partnered with Janssen to bring this revolutionary drug to patients across the United States and throughout the world. Janssen, recognizing the potential of the compound, invested hundreds of millions of dollars in the clinical development and commercialization of IMBRUVICA®.

5. Initial clinical trials using IMBRUVICA® to treat mantle cell lymphoma ("MCL") showed that patients taking IMBRUVICA® had an observed response rate of 68%. These results led FDA to grant accelerated approval to IMBRUVICA® for the treatment of MCL in patients who had received at least one prior therapy through the new Breakthrough Therapy Designation pathway, a process that allows the FDA to grant priority review to drug candidates if preliminary clinical trials indicate that the therapy may offer substantial treatment advantages over existing

options for patients with serious or life-threatening diseases. IMBRUVICA® was one of the first drugs ever to receive FDA approval via the Breakthrough Therapy Designation.

6. IMBRUVICA® has received three additional Breakthrough Therapy Designations for three additional indications: Waldenström's macroglobulinemia; chronic lymphocytic leukemia ("CLL") or small lymphocytic lymphoma ("SLL") with a deletion of the short arm of chromosome 17 (del 17p); and chronic graft-versus-host-disease ("cGVHD"). IMBRUVICA® is also indicated for the treatment of marginal zone lymphoma ("MZL") in patients who require systemic therapy and have received at least one prior anti-CD20-based therapy and the treatment of CLL/SLL. For MZL and cGVHD, IMBRUVICA® represents the first FDA approved treatment specifically for patients with these disorders.

7. IMBRUVICA® has one of the most robust clinical oncology development programs for a single molecule in the industry, with more than 130 ongoing clinical trials. There are approximately 30 ongoing company-sponsored trials, 14 of which are in Phase 3, and more than 100 investigator-sponsored trials and external collaborations that are active around the world.

8. IMBRUVICA® has gained widespread acceptance in the medical community with more than 135,000 patients around the world having been treated with IMBRUVICA®. In 2015, IMBRUVICA® was awarded the prestigious Prix Galien Award for Best Pharmaceutical Agent. The Prix Galien Award is considered the biomedical industry's highest accolade.

9. The '753, '455, '999, '881, '883, '140 and '548 Patents are listed in the Orange Book for IMBRUVICA®.

THE PARTIES

10. Plaintiff Pharmacyclics LLC is a limited liability company organized and existing under the laws of the Delaware with its principal place of business at 999 East Arques Avenue,

Sunnyvale, California 94085. Pharmacyclics is a wholly owned subsidiary of AbbVie Inc., a Delaware corporation with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064-6400. Pharmacyclics is the assignee and owner of the '753, '455, '999, '881, '883, '140 and '548 Patents. Pharmacyclics holds New Drug Application ("NDA") No. 205552 for IMBRUVICA®.

11. Plaintiff Janssen Biotech, Inc. is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044. Janssen is a wholly owned subsidiary of Johnson & Johnson. Janssen is the exclusive licensee of the Orange Book patents for IMBRUVICA®. Janssen is engaged in the clinical development and commercialization of IMBRUVICA® and shares in the proceeds from U.S. sales of IMBRUVICA®.

12. On information and belief, Defendant Shilpa is a corporation organized and existing under the laws of India, with a principal place of business at 12-6-214/A-1 Hyderabad Road, Raichur – 584 135, Karnataka, India.

13. On information and belief, Shilpa caused ANDA No. 211261 to be submitted to FDA and seeks FDA approval of ANDA No. 211261.

14. On information and belief, Shilpa holds Drug Master File ("DMF") No. 32122 for ibrutinib.

15. On information and belief, Shilpa intends to commercially manufacture, market, offer for sale, and sell the proposed generic ibrutinib capsules described in Shilpa's ANDA ("Shilpa's ANDA Product") throughout the United States, including in the State of Delaware, in the event FDA approves Shilpa's ANDA.

16. On information and belief, Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, with a principal place of business at Office 43 Block Y, Sharjah Airport International Free Zone, P.O. Box 122304, Sharjah, United Arab Emirates.

17. On information and belief, Sun Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of India, with a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra 400063, India.

18. On information and belief, Sun Pharma Global FZE is a wholly owned subsidiary of Sun Pharmaceutical Industries Ltd.

19. On information and belief, Sun Pharma Global FZE acts at the direction, and for the benefit, of Sun Pharmaceutical Industries Ltd., and is controlled and/or dominated by Sun Pharmaceutical Industries Ltd.

20. On further information and belief, Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On further information and belief, Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE are agents of one another and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

21. On information and belief, Sun caused ANDA No. 211319 to be submitted to FDA and seeks FDA approval of ANDA No. 211319.

22. On information and belief, Sun Pharmaceutical Industries Ltd. holds Drug Master File ("DMF") No. 31547 for ibrutinib.

23. On information and belief, Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE acted collaboratively in the preparation and submission of ANDA No. 211319 and DMF No. 31547 and continue to act collaboratively in pursuing FDA approval of ANDA No. 211319 and seeking to market the proposed generic ibrutinib capsules.

24. On information and belief, Sun intends to commercially manufacture, market, offer for sale, and sell the proposed generic ibrutinib capsules described in Sun's ANDA ("Sun's ANDA Product") throughout the United States, including in the State of Delaware, in the event FDA approves Sun's ANDA.

25. On information and belief, Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. rely on material assistance from one another to market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of Delaware. On information and belief, Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Sun's ANDA Product, in the event FDA approves Sun's ANDA.

JURISDICTION AND VENUE

26. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271.

27. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338. *See also Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1123–25 (Fed. Cir. 2018).

28. This Court has personal jurisdiction over Shilpa because, on information and belief, Shilpa, *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the

privilege of doing business in the State of Delaware, and intends to sell its ANDA Product in the State of Delaware upon approval of ANDA No. 211261.

29. On information and belief, Shilpa is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter-egos, throughout the United States and in this judicial district.

30. Shilpa has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture and/or market IMBRUVICA® for sale and use throughout the United States, including in this judicial district. On information and belief and as indicated by a letter dated December 28, 2017 sent by Shilpa Medicare Limited to Pharmacyclics pursuant to 21 U.S.C. § 355(j)(2)(B) ("Shilpa's Notice Letter"), Shilpa prepared and filed its ANDA with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

31. On information and belief, Shilpa plans to sell its ANDA Product in the State of Delaware, list its ANDA Product on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of its ANDA Product in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

32. On information and belief, Shilpa knows and intends that its proposed ANDA Product will be distributed and sold in Delaware and will thereby displace sales of IMBRUVICA®, causing injury to Plaintiffs. Shilpa intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed ANDA Product.

33. Shilpa has engaged in patent litigation concerning FDA-approved drug products in this judicial district and has not contested personal jurisdiction or venue in this judicial district in such litigation. *See Biogen MA Inc. v. Shilpa Medicare Limited*, 1:17-cv-00847-LPS, D.I. 8 (D. Del. Oct. 16, 2017).

34. Shilpa has not contested personal jurisdiction in this judicial district in this action. *See* C.A. No. 18-237, D.I. 24, Answer ¶ 31 ("Shilpa does not contest personal jurisdiction in this Court.").

35. Shilpa has invoked the jurisdiction of this judicial district as a Counterclaimant in this action. *See* C.A. No. 18-237, D.I. 24, Counterclaims ¶ 4.

36. Alternatively, this Court has personal jurisdiction over Shilpa because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Shilpa is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Shilpa has sufficient contacts in the United States as a whole, including, but not limited to, preparing and submitting an ANDA to FDA, preparing and submitting DMF No. 32122 to FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Shilpa satisfies due process.

37. Venue is proper in this district for Shilpa pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Shilpa is a corporation organized and existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

38. Shilpa has not contested venue in this judicial district in this action. *See* C.A. No. 18-237, D.I. 24, Answer ¶ 27 ("Shilpa does not contest venue in this judicial district.").

39. This Court has personal jurisdiction over Sun because, on information and belief, Sun, *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Sun's ANDA Product in the State of Delaware upon approval of ANDA No. 211319.

40. On information and belief, Sun is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Sun manufactures, distributes, markets and/or sells throughout the United States and in this judicial district.

41. On information and belief, Sun is licensed to sell generic and proprietary pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

42. Sun has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture and/or market IMBRUVICA® for sale and use throughout the United States, including in this judicial district. On information and belief and as indicated by a letter dated January 2, 2018 sent by Sun Pharma Global FZE to, *inter alia*, Pharmacyclics and Janssen pursuant to 21 U.S.C. § 355(j)(2)(B) ("Sun's First Notice Letter"); and a letter dated February 7, 2019 sent by Sun Pharma Global FZE to, *inter alia*, Pharmacyclics and Janssen pursuant to 21 U.S.C. § 355(j)(2)(B) ("Sun's Second Notice Letter"), Sun prepared and filed its

ANDA with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

43. On information and belief, Sun plans to sell its ANDA Product in the State of Delaware, list its ANDA Product on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of its ANDA Product in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

44. On information and belief, Sun knows and intends that its proposed ANDA Product will be distributed and sold in Delaware and will thereby displace sales of IMBRUVICA®, causing injury to Plaintiffs. Sun intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed ANDA Product.

45. Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE have engaged in patent litigation concerning FDA-approved drug products in this judicial district and have not contested personal jurisdiction or venue in this judicial district in such litigation. *See, e.g.*, *Biogen MA Inc. v. Sun Pharma Global FZE*, 17-cv-00848, D.I. 9 (D. Del. Oct. 16, 2017); *Bristol-Myers Squibb Co. et al v. Sun Pharmaceutical Industries, Inc. et al.*, 17-cv-00409, D.I. 10 (D. Del. May 12, 2017); *Amgen Inc. v. Sun Pharmaceutical Industries, Ltd., et al.*, 16-cv-00882, D.I. 14 (D. Del. Nov. 16, 2016).

46. Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE have not contested personal jurisdiction in this judicial district in this action. *See* C.A. No. 18-237, D.I. 14, Answer ¶ 38 ("Sun does not contest personal jurisdiction in this Court."); C.A. No. 18-1543, D.I. 9, Answer ¶ 26 ("Sun does not contest personal jurisdiction in this Court.").

47. Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE have invoked the jurisdiction of this judicial district as a Counterclaimant in this action. *See* C.A. No. 18-237, D.I. 14, Counterclaims ¶ 10; C.A. No. 18-1543, D.I. 9, Counterclaims ¶ 10.

48. Alternatively, this Court has personal jurisdiction over Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE have sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Sun's ANDA to FDA, preparing and submitting DMF No. 31547 to FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE satisfies due process.

49. Venue is proper in this district for Sun Pharma Global FZE pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

50. Venue is proper in this district for Sun Pharmaceutical Industries Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sun Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of India and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

51. Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE have not contested venue in this judicial district in this action. *See* C.A. No. 18-237, D.I. 14, Answer ¶ 44 ("Sun does not contest venue in this Court."); C.A. No. 18-1543, D.I. 9, Answer ¶ ("Sun does not contest venue in this Court.").

THE ASSERTED PATENTS

52. The '753 Patent, entitled "Crystalline Forms of a Bruton's Tyrosine Kinase Inhibitor," was duly and lawfully issued by the USPTO on March 29, 2016. A true and correct copy of the '753 Patent is attached hereto as Exhibit A.

53. The '455 Patent, entitled "Crystalline Forms of a Bruton's Tyrosine Kinase Inhibitor," was duly and lawfully issued by the USPTO on August 8, 2017. A true and correct copy of the '455 Patent is attached hereto as Exhibit B.

54. The '999 Patent, entitled "Use of Inhibitors of Bruton's Tyrosine Kinase (BTK)," was duly and lawfully issued by the USPTO on April 7, 2015. A true and correct copy of the '999 Patent is attached hereto as Exhibit C.

55. The '881 Patent, entitled "Use of Inhibitors of Bruton's Tyrosine Kinase (BTK)," was duly and lawfully issued by the USPTO on October 31, 2017. A true and correct copy of the '881 Patent is attached hereto as Exhibit D.

56. The '883 Patent, entitled "Use of Inhibitors of Bruton's Tyrosine Kinase (BTK)," was duly and lawfully issued by the USPTO on October 31, 2017. A true and correct copy of the '883 Patent is attached hereto as Exhibit E.

57. The '140 Patent, entitled "Crystalline Forms of a Bruton's Tyrosine Kinase Inhibitor," was duly and lawfully issued by the USPTO on November 13, 2018. A true and correct copy of the '140 Patent is attached hereto as Exhibit F.

58. The ’548 Patent, entitled “Crystalline Forms of a Bruton’s Tyrosine Kinase Inhibitor,” was duly and lawfully issued by the USPTO on October 23, 2018. A true and correct copy of the ’548 Patent is attached hereto as Exhibit G.

SHILPA’S ANDA NO. 211261

59. On information and belief, Shilpa has submitted ANDA No. 211261 to FDA, or caused ANDA No. 211261 to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of ibrutinib capsules as a purported generic version of IMBRUVICA® prior to the expiration of the ’753, ’455, ’140, and ’548 Patents.

60. On information and belief, FDA has not approved Shilpa’s ANDA.

61. On information and belief, Shilpa sent Pharmacyclics a Notice Letter dated December 28, 2017. Shilpa’s Notice Letter represented that Shilpa had submitted to FDA ANDA No. 211261 and a purported Paragraph IV certification for the ’753 and ’455 Patents.

62. According to applicable regulations, Notice Letters such as Shilpa’s must contain a detailed statement of the factual and legal basis for the applicant’s opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing “for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” *See* 21 CFR § 314.95(c)(7); *see also* 21 CFR § 314.52.

63. Shilpa’s Notice Letter did not allege that any claim of the ’753 and ’455 Patents is invalid or unenforceable.

64. On information and belief, if FDA approves Shilpa’s ANDA, Shilpa will manufacture, offer for sale, or sell its ANDA Product, within the United States, including within

the State of Delaware, or will import its ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Shilpa's ANDA Product will directly infringe the '753, '455, '140, and '548 Patents and Shilpa will actively induce and/or contribute to their infringement.

65. On February 1, 2018, Shilpa produced what it purported to be ANDA No. 211261 and portions of DMF No. 32122 to counsel for Pharmacyclics and Janssen. Immediately upon reviewing the materials produced by Shilpa, Plaintiffs informed Shilpa that Shilpa's Notice Letter is inconsistent with information in Shilpa's production. For example, Shilpa's Notice Letter alleges that Shilpa's ANDA Product does not infringe the '753 and '455 Patents on the basis of data in the letter. That data, however, was not in Shilpa's ANDA or DMF as produced to Plaintiffs. Plaintiffs requested that Shilpa explain the disparity between Shilpa's Notice Letter and its ANDA and DMF, and produce additional documents necessary to evaluate Shilpa's claims of non-infringement of the '753 and '455 Patents described in Shilpa's Notice Letter.

66. In response, Shilpa represented that it produced its entire ANDA and stated that Shilpa had "no comments" to Plaintiffs' inquiries concerning its Notice Letter and ANDA and DMF. On February 8, 2018, Shilpa produced two additional documents. These documents did not resolve the inconsistencies between Shilpa's Notice Letter and Shilpa's production. Plaintiffs informed Shilpa that the additional documents are inconsistent with the information and representations in Shilpa's ANDA and requested an explanation for the disparity between Shilpa's ANDA and the documents produced to Plaintiffs. Shilpa "reiterate[d]" that it had "no comments" in response to Plaintiffs' inquiries.

67. Plaintiffs initially brought this action within forty-five days of receipt of Shilpa's Notice Letter, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

68. After Plaintiffs initially brought this action, the '140 and '548 Patents were listed in the Orange Book for IMBRUVICA®. Pursuant to 21 CFR § 314.94(a)(12)(viii)(C)(1)(ii), Shilpa must submit a certification for the '140 and '548 Patents in connection with ANDA No. 211261 before obtaining FDA approval of the ANDA. On information and belief, Shilpa has not submitted a Paragraph III certification for the '140 and '548 Patents. Shilpa has submitted a Paragraph IV certification in connection with ANDA No. 211261 for patents related to the '140 and '548 Patents. On information and belief, Shilpa intends to seek permission from FDA to market its ANDA Product prior to expiration of the '140 and '548 Patents. Plaintiffs bring this First Amended Complaint to assert infringement of the '140 and '548 Patents in addition to the patents originally asserted against Shilpa.

69. On January 9, 2019, Plaintiffs requested Shilpa's consent to file this First Amended Complaint with counts for infringement of the '140 and '548 Patents. On January 29, 2019, Shilpa provided written consent to the filing of this First Amended Complaint with counts of infringement of the '140 and '548 Patents.

70. This First Amended Complaint is timely filed prior to the August 16, 2019 deadline for amended pleadings as set forth in the Scheduling Order. C.A. No. 18-192, D.I. 85 at 1.

SUN'S ANDA NO. 211319

71. On information and belief, Sun has submitted ANDA No. 211319 to FDA, or caused ANDA No. 211319 to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of ibrutinib capsules as a

purported generic version of IMBRUVICA® prior to the expiration of the '753, '455, '999, '881, '883, '140, and '548 Patents.

72. On information and belief, FDA has not approved Sun's ANDA.

73. On information and belief, Sun sent Pharmacyclics and Janssen a First Notice Letter dated January 2, 2018. Sun's First Notice Letter represented that Sun had submitted to FDA ANDA No. 211319 and a purported Paragraph IV certification for the '753, '455, '999, '881, and '883 Patents.

74. Sun Pharma Global FZE sent Pharmacyclics and Janssen a Second Notice Letter dated February 7, 2019. The Second Notice Letter represented that Sun Pharma Global FZE had submitted to FDA ANDA No. 211319 and a purported Paragraph IV certification for the '140 and '548 Patents.

75. On information and belief, if FDA approves Sun's ANDA, Sun will manufacture, offer for sale, or sell its ANDA Product, within the United States, including within the State of Delaware, or will import its ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Sun's ANDA Product will directly infringe the '753, '455, '999, '881, '883, '140, and '548 Patents and Sun will actively induce and/or contribute to their infringement.

76. Plaintiffs initially brought this action within forty-five days of receipt of Sun's Notice Letter, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii). The First Amended Complaint is being brought within forty-five days of Plaintiffs' receipt of Sun's Second Notice Letter.

77. On January 9, 2019, Plaintiffs requested Sun's consent to file this First Amended Complaint with counts for infringement of the '140 and '548 Patents. On January 29, 2019 and February 11, 2019, Sun provided written consent to the filing of this First Amended Complaint with counts of infringement of the '140 and '548 Patents.

78. This First Amended Complaint is timely filed prior to the August 16, 2019 deadline for amended pleadings as set forth in the Scheduling Order. C.A. No. 18-192, D.I. 85 at 1.

COUNT I
INFRINGEMENT OF THE '753 PATENT BY SHILPA

79. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–78 as if fully set forth herein.

80. On information and belief, Shilpa submitted or caused the submission of ANDA No. 211261 to FDA, and thereby seeks FDA approval of Shilpa's ANDA Product.

81. Plaintiffs own all rights, title, and interest in and to the '753 Patent.

82. Shilpa's ANDA Product infringes one or more claims of the '753 Patent.

83. Shilpa did not contend that claims 1–18 of '753 Patent are invalid or unenforceable in Shilpa's Notice Letter. If Shilpa had a factual or legal basis to contend that the claims of the '753 Patent are invalid or unenforceable, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

84. The information that Shilpa relied on to support its claim of non-infringement of the '753 Patent in its Notice Letter was not contained in its ANDA.

85. Shilpa has infringed one or more claims of the '753 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211261 with a Paragraph IV certification and thereby

seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '753 Patent.

86. On information and belief, the importation, manufacture, sale, offer for sale, or use of Shilpa's ANDA Product prior to the expiration of the '753 Patent would infringe one or more claims of the '753 Patent under 35 U.S.C. § 271(a), and/or Shilpa would induce the infringement of and/or contribute to the infringement of one or more claims of the '753 Patent under 35 U.S.C. § 271 (b) and/or (c).

87. Shilpa had actual and constructive notice of the '753 Patent prior to filing ANDA No. 211261, and was aware that the filing of ANDA No. 211261 with the request for FDA approval prior to the expiration of the '753 Patent would constitute an act of infringement of the '753 Patent.

88. Shilpa filed its ANDA without adequate justification for asserting that the '753 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Shilpa's conduct in certifying non-infringement with respect to the '753 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

89. Shilpa's Notice Letter relating to its claim of non-infringement of the '753 Patent is inconsistent with information contained in Shilpa's ANDA, which Shilpa represented was produced in its entirety, and its DMF as produced to Plaintiffs. Shilpa provided "no comments" on the disconnect between its Notice Letter and its ANDA and DMF. The inconsistencies between Shilpa's Notice Letter and Shilpa's production remain unresolved.

90. Plaintiffs will be irreparably harmed if Shilpa is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '753 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Shilpa, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
INFRINGEMENT OF THE '455 PATENT BY SHILPA

91. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–90 as if fully set forth herein.

92. On information and belief, Shilpa submitted or caused the submission of ANDA No. 211261 to FDA, and thereby seeks FDA approval of Shilpa's ANDA Product.

93. Plaintiffs own all rights, title, and interest in and to the '455 Patent.

94. Shilpa's ANDA Product infringes one or more claims of the '455 Patent.

95. Shilpa did not contend that claims 1–13 of the '455 Patent are invalid or unenforceable in Shilpa's Notice Letter. If Shilpa had a factual or legal basis to contend that the claims of the '455 Patent are invalid or unenforceable, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

96. The information that Shilpa relied on to support its claim of non-infringement of the '455 Patent in its Notice Letter was not contained in its ANDA.

97. Shilpa has infringed one or more claims of the '455 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211261 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '455 Patent.

98. On information and belief, the importation, manufacture, sale, offer for sale, or use of Shilpa's ANDA Product prior to the expiration of the '455 Patent would infringe one or more claims of the '455 Patent under 35 U.S.C. § 271(a), and/or Shilpa would induce the infringement of and/or contribute to the infringement of one or more claims of the '455 Patent under 35 U.S.C. § 271 (b) and/or (c).

99. Shilpa had actual and constructive notice of the '455 Patent prior to filing ANDA No. 211261, and was aware that the filing of ANDA No. 211261 with the request for FDA approval prior to the expiration of the '455 Patent would constitute an act of infringement of the '455 Patent.

100. Shilpa filed its ANDA without adequate justification for asserting that the '455 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Shilpa's conduct in certifying non-infringement with respect to the '455 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

101. Shilpa's Notice Letter relating to its claim of non-infringement of the '455 Patent is inconsistent with information contained in Shilpa's ANDA, which Shilpa represented was produced in its entirety, and its DMF as produced to Plaintiffs. Shilpa provided "no comments" on the disconnect between its Notice Letter and its ANDA and DMF. The inconsistencies between Shilpa's Notice Letter and Shilpa's production remain unresolved.

102. Plaintiffs will be irreparably harmed if Shilpa is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '455 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and

Shilpa, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT III
INFRINGEMENT OF THE '140 PATENT BY SHILPA

103. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–102 as if fully set forth herein.

104. On information and belief, Shilpa submitted or caused the submission of ANDA No. 211261 to FDA, and thereby seeks FDA approval of Shilpa's ANDA Product.

105. Plaintiffs own all rights, title, and interest in and to the '140 Patent.

106. Shilpa's ANDA Product infringes one or more claims of the '140 Patent.

107. Shilpa has infringed one or more claims of the '140 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211261 and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '140 Patent. Subject matter jurisdiction over this Count exists pursuant to 35 U.S.C. § 271(e)(2)(A) and 28 U.S.C. § 1338(a). *See Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1123–25 (Fed. Cir. 2018).

108. The '140 Patent is listed in the Orange Book for NDA No. 205552. Pursuant to 21 CFR § 314.94(a)(12)(viii)(C)(1)(ii), Shilpa must submit a certification for the '140 Patent in connection with ANDA No. 211261 before obtaining FDA approval of the ANDA. On information and belief, Shilpa has not submitted a Paragraph III certification for the '140 Patent. Shilpa has submitted a Paragraph IV certification in connection with ANDA No. 211261 for patents related to the '140 Patent. On information and belief, Shilpa intends to seek permission from FDA to market its ANDA Product prior to expiration of the '140 Patent. Accordingly, a case or controversy exists between the parties regarding Shilpa's infringement of the '140 Patent.

109. On information and belief, the importation, manufacture, sale, offer for sale, or use of Shilpa's ANDA Product prior to the expiration of the '140 Patent would infringe one or more claims of the '140 Patent under 35 U.S.C. § 271(a), and/or Shilpa would induce the infringement of and/or contribute to the infringement of one or more claims of the '140 Patent under 35 U.S.C. § 271 (b) and/or (c).

110. On information and belief, Shilpa continues to seek approval of its ANDA without adequate justification for asserting that the '140 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Shilpa's conduct renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

111. Plaintiffs will be irreparably harmed if Shilpa is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '140 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Shilpa, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV
INFRINGEMENT OF THE '548 PATENT BY SHILPA

112. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–111 as if fully set forth herein.

113. On information and belief, Shilpa submitted or caused the submission of ANDA No. 211261 to FDA, and thereby seeks FDA approval of Shilpa's ANDA Product.

114. Plaintiffs own all rights, title, and interest in and to the '548 Patent.

115. Shilpa's ANDA Product infringes one or more claims of the '548 Patent.

116. Shilpa has infringed one or more claims of the '548 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211261 and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '548 Patent. Subject matter jurisdiction over this Count exists pursuant to 35 U.S.C. § 271(e)(2)(A) and 28 U.S.C. § 1338(a). *See Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1123–25 (Fed. Cir. 2018).

117. The '548 Patent is listed in the Orange Book for NDA No. 205552. Pursuant to 21 CFR § 314.94(a)(12)(viii)(C)(1)(ii), Shilpa must submit a certification for the '548 Patent in connection with ANDA No. 211261 before obtaining FDA approval of the ANDA. On information and belief, Shilpa has not submitted a Paragraph III certification for the '548 Patent. Shilpa has submitted a Paragraph IV certification in connection with ANDA No. 211261 for patents related to the '548 Patent. On information and belief, Shilpa intends to seek permission from FDA to market its ANDA Product prior to expiration of the '548 Patent. Accordingly, a case or controversy exists between the parties regarding Shilpa's infringement of the '548 Patent.

118. On information and belief, the importation, manufacture, sale, offer for sale, or use of Shilpa's ANDA Product prior to the expiration of the '548 Patent would infringe one or more claims of the '548 Patent under 35 U.S.C. § 271(a), and/or Shilpa would induce the infringement of and/or contribute to the infringement of one or more claims of the '548 Patent under 35 U.S.C. § 271 (b) and/or (c).

119. On information and belief, Shilpa continues to seek approval of its ANDA without adequate justification for asserting that the '548 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Shilpa's conduct renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and

entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

120. Plaintiffs will be irreparably harmed if Shilpa is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '548 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Shilpa, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT V
INFRINGEMENT OF THE '753 PATENT BY SUN

121. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–120 as if fully set forth herein.

122. On information and belief, Sun submitted or caused the submission of ANDA No. 211319 to FDA, and thereby seeks FDA approval of Sun's ANDA Product.

123. Plaintiffs own all rights, title, and interest in and to the '753 Patent.

124. Sun's ANDA Product infringes one or more claims of the '753 Patent.

125. Sun has infringed one or more claims of the '753 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211319 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '753 Patent.

126. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '753 Patent would infringe one or more claims of the '753 Patent under 35 U.S.C. § 271(a), and/or Sun would induce the infringement of and/or contribute to the infringement of one or more claims of the '753 Patent under 35 U.S.C. § 271 (b) and/or (c).

127. Sun had actual and constructive notice of the '753 Patent prior to filing ANDA No. 211319, and was aware that the filing of ANDA No. 211319 with the request for FDA approval prior to the expiration of the '753 Patent would constitute an act of infringement of the '753 Patent.

128. Sun filed its ANDA without adequate justification for asserting that the '753 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Sun's conduct in certifying invalidity and/or non-infringement with respect to the '753 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

129. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '753 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Sun, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VI
INFRINGEMENT OF THE '455 PATENT BY SUN

130. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–129 as if fully set forth herein.

131. On information and belief, Sun submitted or caused the submission of ANDA No. 211319 to FDA, and thereby seeks FDA approval of Sun's ANDA Product.

132. Plaintiffs own all rights, title, and interest in and to the '455 Patent.

133. Sun's ANDA Product infringes one or more claims of the '455 Patent.

134. Sun has infringed one or more claims of the '455 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211319 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '455 Patent.

135. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '455 Patent would infringe one or more claims of the '455 Patent under 35 U.S.C. § 271(a), and/or Sun would induce the infringement of and/or contribute to the infringement of one or more claims of the '455 Patent under 35 U.S.C. § 271 (b) and/or (c).

136. Sun had actual and constructive notice of the '455 Patent prior to filing ANDA No. 211319, and was aware that the filing of ANDA No. 211319 with the request for FDA approval prior to the expiration of the '455 Patent would constitute an act of infringement of the '455 Patent.

137. Sun filed its ANDA without adequate justification for asserting that the '455 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Sun's conduct in certifying invalidity and/or non-infringement with respect to the '455 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

138. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '455 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and

Sun, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VII
INFRINGEMENT OF THE '999 PATENT BY SUN

139. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–138 as if fully set forth herein.

140. On information and belief, Sun submitted or caused the submission of ANDA No. 211319 to FDA, and thereby seeks FDA approval of Sun's ANDA Product.

141. Plaintiffs own all rights, title, and interest in and to the '999 Patent.

142. Sun's ANDA Product infringes one or more claims of the '999 Patent.

143. Sun has infringed one or more claims of the '999 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211319 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '999 Patent.

144. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '999 Patent would infringe one or more claims of the '999 Patent under 35 U.S.C. § 271(a), and/or Sun would induce the infringement of and/or contribute to the infringement of one or more claims of the '999 Patent under 35 U.S.C. § 271 (b) and/or (c).

145. Sun had actual and constructive notice of the '999 Patent prior to filing ANDA No. 211319, and was aware that the filing of ANDA No. 211319 with the request for FDA approval prior to the expiration of the '999 Patent would constitute an act of infringement of the '999 Patent.

146. Sun filed its ANDA without adequate justification for asserting that the '999 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Sun's conduct in certifying invalidity and/or non-infringement with respect to the '999 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

147. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '999 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Sun, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VIII
INFRINGEMENT OF THE '881 PATENT BY SUN

148. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–147 as if fully set forth herein.

149. On information and belief, Sun submitted or caused the submission of ANDA No. 211319 to FDA, and thereby seeks FDA approval of Sun's ANDA Product.

150. Plaintiffs own all rights, title, and interest in and to the '881 Patent.

151. Sun's ANDA Product infringes one or more claims of the '881 Patent.

152. Sun has infringed one or more claims of the '881 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211319 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '881 Patent.

153. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '881 Patent would infringe one or more claims of the '881 Patent under 35 U.S.C. § 271(a), and/or Sun would induce the infringement of and/or contribute to the infringement of one or more claims of the '881 Patent under 35 U.S.C. § 271 (b) and/or (c).

154. Sun had actual and constructive notice of the '881 Patent prior to filing ANDA No. 211319, and was aware that the filing of ANDA No. 211319 with the request for FDA approval prior to the expiration of the '881 Patent would constitute an act of infringement of the '881 Patent.

155. Sun filed its ANDA without adequate justification for asserting that the '881 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Sun's conduct in certifying invalidity and/or non-infringement with respect to the '881 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

156. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '881 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Sun, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IX
INFRINGEMENT OF THE '883 PATENT BY SUN

157. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–156 as if fully set forth herein.

158. On information and belief, Sun submitted or caused the submission of ANDA No. 211319 to FDA, and thereby seeks FDA approval of Sun's ANDA Product.

159. Plaintiffs own all rights, title, and interest in and to the '883 Patent.

160. Sun's ANDA Product infringes one or more claims of the '883 Patent.

161. Sun has infringed one or more claims of the '883 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211319 with a Paragraph IV certification and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '883 Patent.

162. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '883 Patent would infringe one or more claims of the '883 Patent under 35 U.S.C. § 271(a), and/or Sun would induce the infringement of and/or contribute to the infringement of one or more claims of the '883 Patent under 35 U.S.C. § 271 (b) and/or (c).

163. Sun had actual and constructive notice of the '883 Patent prior to filing ANDA No. 211319, and was aware that the filing of ANDA No. 211319 with the request for FDA approval prior to the expiration of the '883 Patent would constitute an act of infringement of the '883 Patent.

164. Sun filed its ANDA without adequate justification for asserting that the '883 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Sun's conduct in certifying invalidity and/or non-infringement with respect to the '883 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

165. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '883 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Sun, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT X
INFRINGEMENT OF THE '140 PATENT BY SUN

166. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–165 as if fully set forth herein.

167. On information and belief, Sun submitted or caused the submission of ANDA No. 211319 to FDA, and thereby seeks FDA approval of Sun's ANDA Product.

168. Plaintiffs own all rights, title, and interest in and to the '140 Patent.

169. Sun's ANDA Product infringes one or more claims of the '140 Patent.

170. Sun has infringed one or more claims of the '140 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211319 and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '140 Patent.

171. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '140 Patent would infringe one or more claims of the '140 Patent under 35 U.S.C. § 271(a), and/or Sun would induce the infringement of and/or contribute to the infringement of one or more claims of the '140 Patent under 35 U.S.C. § 271 (b) and/or (c).

172. On information and belief, Sun continues to seek approval of its ANDA without adequate justification for asserting that the '140 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Sun's

conduct renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

173. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '140 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Sun, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XI
INFRINGEMENT OF THE '548 PATENT BY SUN

174. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–173 as if fully set forth herein.

175. On information and belief, Sun submitted or caused the submission of ANDA No. 211319 to FDA, and thereby seeks FDA approval of Sun's ANDA Product.

176. Plaintiffs own all rights, title, and interest in and to the '548 Patent.

177. Sun's ANDA Product infringes one or more claims of the '548 Patent.

178. Sun did not contest infringement of claims 26–28 of the '548 Patent in Sun's Second Notice Letter. If Sun had a factual or legal basis to contest infringement of the claims of the '548 Patent, it was required by applicable regulations to state such a basis in that Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

179. Sun has infringed one or more claims of the '548 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211319 and thereby seeking FDA approval of a generic version of IMBRUVICA® prior to the expiration of the '548 Patent.

180. On information and belief, the importation, manufacture, sale, offer for sale, or use of Sun's ANDA Product prior to the expiration of the '548 Patent would infringe one or

more claims of the '548 Patent under 35 U.S.C. § 271(a), and/or Sun would induce the infringement of and/or contribute to the infringement of one or more claims of the '548 Patent under 35 U.S.C. § 271 (b) and/or (c).

181. On information and belief, Sun continues to seek approval of its ANDA without adequate justification for asserting that the '548 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of its ANDA Product. Sun's conduct renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

182. Plaintiffs will be irreparably harmed if Sun is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '548 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Sun, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment that Shilpa has infringed the '753, '455, '140 and '548 Patents under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment that Sun has infringed the '753, '455, '999, '881, '883, '140 and '548 Patents under 35 U.S.C. § 271(e)(2)(A);

(C) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Shilpa's ANDA shall be no earlier than the last expiration date of any of the '753, '455, '140 or '548 Patents, or any later expiration of exclusivity for any of the '753, '455, '140 or '548 Patents, including any extensions or regulatory exclusivities;

(D) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Sun's ANDA shall be no earlier than the last expiration date of any of the '753, '455, '999, '881, '883, '140 or '548 Patents, or any later expiration of exclusivity for any of the '753, '455, '999, '881, '883, '140 or '548 Patents, including any extensions or regulatory exclusivities;

(E) Entry of a permanent injunction enjoining Shilpa, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Shilpa or on its behalf from commercially manufacturing, using, offering for sale, or selling its ANDA Product within the United States, or importing its ANDA Product into the United States, until the day after the expiration of the '753, '455, '140 and '548 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the '753, '455, '140 and '548 Patents;

(F) Entry of a permanent injunction enjoining Sun, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Sun or on its behalf from commercially manufacturing, using, offering for sale, or selling its ANDA Product within the United States, or importing its ANDA Product into the United States, until the day after the expiration of the '753, '455, '999, '881, '883, '140 and '548 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the '753, '455, '999, '881, '883, '140 and '548 Patents;

(G) A judgment declaring that making, using, selling, offering to sell, or importing Shilpa's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the '753, '455, '140 and '548 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(H) A judgment declaring that making, using, selling, offering to sell, or importing Sun's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the '753, '455, '999, '881, '883, '140 and '548 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(I) A declaration under 28 U.S.C. § 2201 that if Shilpa, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Shilpa's ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(J) A declaration under 28 U.S.C. § 2201 that if Sun, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Sun's ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(K) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Shilpa engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product, or any product that infringes the '753, '455, '140 or '548 Patents, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

(L) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Sun engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product, or any product that infringes the '753, '455, '999, '881, '883, '140 or '548 Patents, or

induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

(M) A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(N) Costs and expenses in this action; and

(O) Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
jtigan@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Christopher N. Sipes
Erica N. Andersen
Brianne Bharkhda
Chanson Chang
Nicholas L. Evoy
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

Attorneys for Pharmacyclics LLC

Gregory L. Diskant
Irena Royzman
Jordan M. Engelhardt
Lachlan Campbell-Verduyn
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
(212) 336-2000

Attorneys for Janssen Biotech, Inc.

February 12, 2019